DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 29, 2014

EpiEP, Inc.
% Elsa Abruzzo
President & CEO
Cygnus Regulatory, LLC
8 Grandin Lane
Cincinnati, Ohio 45208

Re: K142245
Trade/Device Name: EpiAccess System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRS, DXG
Dated: August 11, 2014
Received: August 13, 2014

Dear Elsa Abruzzo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K142245

Device Name: EpiAccess System

Indications for Use:

The EpiAccess System with introducer needle and integrated needle tip pressure transducer is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate guidewire placement into the pericardial space in electrophysiology procedures in adult patients.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

510(k) SUMMARY
EpiEP, Inc.'s EpiAccess System

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

EpiEP, Inc.
Phone: 513-236-0857
Facsimile: 513-898-2106

Contact Person: Elsa Chi Abruzzo, RAC, FRAPS
Date Prepared: October 21, 2014

Name/Address of Sponsor

EpiEP, Inc.
142 Temple Street, Suite 206
New Haven, CT 06510, USA

Trade Name:	EpiAccess System
Common or Usual Name	Epicardial Introducer System
Classification Name	Introducer, Catheter Extravascular Blood Pressure Transducer Single-Function, Preprogrammed Diagnostic Computer
Classification:	Class II
Product Code and Regulation:	DYB, 21 CFR 870.1340 DRS, 21 CFR 870.2850 DXG, 21 CFR 870.1435
Classification Panel:	Cardiovascular

Predicate Devices:

St Jude Medical	Agilis PF Introducer System and Accessories	K111943
Mirador Biomedical. Inc.	Compass™ GP Compass™ Thoracentesis Compass™ Paracentesis Compass™ Compartment Pressure Compass™ Epidural Assist Compass™ Arterial Assist	K112203

Intended Use / Indications for Use

The EpiAccess System with introducer needle and integrated needle tip pressure transducer is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate guidewire placement into the pericardial space in electrophysiology procedures in adult patients.

Technological Characteristics

The EpiAccess System consists of the following components and accessories: a sterile, single-use (disposable) Tuohy Type Needle with an integrated, distal, needle tip pressure transducer (sensor), and a reusable integrated Control Unit that includes pre-programmed diagnostic computer with a touchscreen display and graphical user interface (GUI).

The subject EpiAccess Needle is very similar or the same in design, dimensions, materials, packaging, sterilization, and intended use to the, primary predicate, the St. Jude Agilis PF Introducer. With the exception of minor dimensional differences and addition of an integrated (non-patient contacting) fiber optic pressure transducer, the EpiAccess Needle has the same technological characteristics as the predicate introducer needle and same intended use.

The EpiAccess Control Unit provides the EpiAccess System with the additional convenience feature of integrated, direct physiological pressure measurement at the EpiAccess Needle tip. The EpiAccess Control Unit also receives input from commercially available arterial line (A-line) catheters and commercially available A-line pressure transducers. These accessories are readily available standard equipment in electrophysiology labs. A-line catheter pressure measurements are routine in electrophysiology procedures. The A-line pressure measurement function is also provided for user convenience and is displayed along with the needle tip pressure measurement on the EpiAccess user interface. The direct physiological pressure measurement functionality and indication is equivalent to that of the secondary predicate the Mirador Compass Digital Pressure Transducers (available in various models for use with various introducer needles for various anatomies).

The EpiAccess System displays the pressure measurement information, which phycians may be able to use to determine needle tip location based on known anatomical pressure differences. This additional information regarding needle tip location is an added convenience feature over standard Tuohy introducer needles for epicardial access. The system does not alert the user to tip location or provide clinical decision guidance. The EpiAccess Needle is placed under visualization with fluoroscopic imaging standard for electrophysiology procedures.

Performance Data

Bench, animal, and clinical tests were conducted on the EpiAccess System to demonstrate that it meets defined design requirements and can perform in a manner equivalent to devices currently on the market used for subxiphoid epicardial access and that provide pressure measurements. Testing included verification and validation testing, comparative usability testing in animals, human factors evaluations per the available guidances, and an assessment of clinical performance.

Manufacturing and traceability of devices tested were conducted in accordance with 21 CFR 820 Good Manufacturing Practices and BS EN ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. In all instances, the EpiAccess System functioned as intended and results observed were as expected. These test results confirm that EpiAccess System is safe, meets the design inputs, and raises no new safety or efficacy concerns. A summary of the EpiAccess Systems design control activities with regards to risk analysis and verification and validation activities is provided in this 510 (k) submission.

Nonclinical testing included:

Dimensional and Performance testing per the applicable sections of:

ISO 594-2: 1998	International Standard – Conical Fittings With 6 (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings
ISO 594-1: 1986	International Standard – Conical Fittings With 6 (Luer) Taper For Syringes, Needles, and Certain Other Medical Equipment – Part 1 General Requirements
ISO 7864: 1993	International Standard – Sterile Hypodermic Needles for Single-Use
ISO 9626: 2001	International Standard – Stainless Steel Needle Tubing for The Manufacture of Medical Devices – Amendment 1
BS EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Electrical Safety and Electromagnetic Compatibility (EMC) per the applicable sections of:

ANSI/AAMI/IEC 60601-1-2:2007	Medical Electrical Equipment – Part1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1 3rd Edition:2012	International Standard – Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance
EN 61000 3-2: 2006	Electromagnetic Compatibility (EMC) Part 3-2: Limits –Limits for Harmonic Current Emissions
EN 61000-3-3: 2008	Electromagnetic Compatibility (EMC) Part 3-3: Limits – Limitation of Voltage Charges, Voltage Fluctuations and flick in low voltage supply systems.

Pressure transducer testing per applicable sections of the recognized standards for product:

AAMI/ANSI BP22:1994 (R) 2011	Blood pressure transducers
IEC 60601-2-34 Edition 3.0 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment

Biocompatibilty Testing per relevant sections of ISO 10993, including:

BS EN ISO 10993-11:2009	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity (ISO 10993-11:2006)
BS EN ISO 10993-4:2009	Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions With Blood
BS EN ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: test for in vitro cytotoxicity
BS EN ISO 10993 -10: 2009	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

Biocompatibilty testing passed for patient contacting materials included:

L929 Neutral Red Uptake Cytotoxicity Test
Kligman Maximization Test
Intracutaneous Injection Test
Systemic Injection Test
Rabbit Pyrogen Test (Material Mediated)
Hemolysis Rabbit Blood
Complement Activation Assay
Unactivated Partial Thromboplastin Time Assay

Sterilization and LAL Pyrogen validation in compliance with applicable sections of:

ANSI/AAMI/ISO 11135-1:2007	Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
ISO 10993-7: 2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
ANSI/AAMI/ISO 11737 -1: 2006	Sterilization of Medical Devices – Microbiological Methods – Part I: Determination of a Population of Microorganisms on Products
ANSI/AAMI/ISO 11737-2: 2009	Sterilization of Medical Devices – Microbiological methods – part 2: Tests of Sterility Performed in the Validation of a Sterilization Process
AAMI TIR: 16:2000	Process development and performance qualification for ethylene oxide sterilization – Microbiological aspects
AAMI ST72: 2002(R) 2010	Bacterial endotoxins – Test methodologies, routine monitoring and alternative to batch testing. (Sterility)
FDA Guidance (Jun 2012)	Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers
FDA Guidance (Dec 12, 2008)	Draft Guidance for Industry and FDA Staff: Submission and Review of Sterility Information in Premarket Notification 510 (k) Submissions for Devices Labeled as Sterile.
FDA Guidance (Aug 30, 2002)	Updated 510 (k) Sterility Review Guidance K90-1: Guidance for Industry and FDA

Shelf Life and Packaging validation in compliance with applicable sections of:

ASTM F88-09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D4169-09	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1929: 2012	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980: 2007	Standard Test Method for Accelerated Aging of Sterile Barrier Systems for a Medical Device
ASTM D5276: 1998	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM D642: 2010	Test method for determining compressive resistance of shipping containers and unit loads
ASTM D999:2008	Test methods for vibration testing of shipping containers
ASTM D6653: 2013	Test methods for Low Pressure (high altitude)
ASTM D4728: 2011	Test methods for random vibration
ASTM D6344: 2009	Test methods for concentrated impacts

Software validation in compliance with applicable sections of:

BS EN ISO 62304:2006	Medical Device Software – Software Life Cycle Processes
FDA Guidance (Jan 11, 2012)	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
FDA Guidance (Sep 9, 1999)	Off-The-Shelf Software Use in Medical Devices

Comparative Animal Studies in compliance with applicable sections of:

21 CRF § 54	Good Laboratory Practices
FDA Guidance (Jul 29, 2010)	Guidance for Industry and FDA Staff: General Considerations for Animal Studies for Cardiovascular Devices

Usability and Human Factors Testing in compliance with applicable sections of:

SI/AAMI HE 75	Human Factors engineering Design of Medical Devices
IEC 62366:2007	Medical Devices - Application of Usability Engineering to Medical Devices
FDA Guidance (Jun 22, 2011)	Human Factors Draft Guidance

Clinical data were obtained via the Epicardial Access Study, A Post Market Clinical Follow-up Study – Europe (EASe) (ClincialTrials.gov Identifier: NCT02209064). This is a European study for the purpose of collecting post marketing data of the CE Marked EpiAccess System. The study subjects are eligible adult patients undergoing epicardial electrophysiology procedures accessed via a minimally invasive subxiphoid approach. The study report supporting this notification summarizes and discusses the clinical results, including technical success (ability to safely access the pericardial space and deliver a guidewire), ease of use and clinical benefit of the pressure frequency information display, and adverse events. To date there has been 100% technical success, no serious adverse events, and no adverse events related to the EpiAccess System.

Clinical testing complies with applicable sections of:

42 U.S.C. 282(j), Section 402(j) of the Public Health Serve Act, enacted by 121 Stat. 823 Public Law 110-85	Compliance with Clinicaltrials.gov registration
ISO 14155:2011	International Standard - Technical Corrigendum 1 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
MEDDEV 2.7.1 Rev 3	Guidelines on Medical Devices - Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
21 CFR Part 50 21 CFR Part 54 21 CFR Part 56	Good Clinical Practices- Human Subject Protection Financial Disclosures By Clinical Investigators Good Clinical Practices – Informed Consent

Substantial Equivalence

The EpiAccess System has the same intended use, and similar indications for use and technological characteristics as the predicate devices. The technological characteristics of the EpiAccess Needle are substantially equivalent to the primary predicate device the St. Jude Medical Agilis PF Introducer System including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device or different question of safety and efficacy.

The addition of integrated pressure measurement at the needle tip for an epicardial introducer needle does not change the overall intended use or raise different questions of safety and efficacy. This additional feature serves the same purpose as other separate pressure wires that can be used in conjunction with the Agilis™ PF predicate, disposable pressure transducer wires/displays that attach to introducer needles, or other devices for epicardial access. The EpiAccess simply offers the user the additional convenience of having this capability integrated with the needle component. The Mirador Compass provides similar pressure measurement capability for use with introducer needles. The addition of this feature, integrated with the EpiAccess needle, enhances user convenience and does not alter the intended use of the EpiAccess System relative to its predicates.

The results from preclinical and clinical testing demonstrate that the technological and performance characteristics of the EpiAccess System meet defined design requirements and can perform in a manner equivalent to devices currently on the market used for epicardial access and guidewire delivery and measuring physiological pressure. Performance data demonstrate that the EpiAccess System performs as intended and is substantially equivalent to its predicates.

Conclusions

The data and information presented within this submission support a determination of substantial equivalence to the predicates listed above, and therefore market clearance of the subject EpiAccess System for its intended use. This conclusion is based upon the device similarities in design, materials technological characteristics, principles of operation, and indications for use.